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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,453	09/19/2003	David T. Hamrick	DSI-10202/22	7278
51279	7590	09/20/2006	EXAMINER	
GIFFORD, KRASS, GROH, SPRINKLE, ANDERSON & CITKOWSKI, P.C. P.O. BOX 7021 TROY, MI 48007-7021			RAO, G NAGESH	
			ART UNIT	PAPER NUMBER
			1722	

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/665,453

Applicant(s)

HAMRICK ET AL.

Examiner

G. Nagesh Rao

Art Unit

1722

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 33-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 and 33-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1-16, 18-19, 21-29 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Levinson (US PG Pub 2002/0177167).

Levinson 167 pertains to a method and system for planning, performing, and assessing high-throughput screening of multicomponent chemical compositions and solid forms of compounds.

Levinson 167 teaches an optimization process capable of being comprised of the following steps selecting a plurality of physical characterization input variables to define a total crystallization experiment permutation number for a crystallant, performing a plurality of crystallization experimental samples, said plurality of crystallization experimental samples being less than the total crystallization experiment permutation number, training a predictive crystallization function through analysis of said plurality of crystallization experimental samples, and

determining an optimal physical crystallization parameter from said predictive crystallization function, and finally storing these optimal parameters and being capable of comparing an unknown crystallization sample to the classification known and stored in the neural network taught in the specification (See Page 1 Section 0004, Page 3 Sections 0019-0025, and Page 4 Section 0039). Furthermore the predictive crystallization function is a neural network, i.e. computer clusters (Figure 6) wherein said crystallant could be a protein crystal wherein a plurality of physical crystallization input variables could be temperature, protein, pH, precipitation, etc...(See Page 19-20 Claims 24-27).

The amended changes to claim 1 incorporating the step process of variables being independent training variables thereafter having dependent variables which are the product of the independent training variables in the form of a plurality of crystallization experimental samples is taught by Levinson 167 (See Sections 0023-0024 and Abstract). Levinson 167 teaches an independent set of parameters which thereafter produce a series of results collected and pooled for a second set of parameters to depend from.

Furthermore the system taught by Levinson 167 would be capable of being programmed and operating said permutation cycles, designating a status of identification for the crystalline sample, creating and building from a database

developed for and by the system and its operators, being able to grow a crystal and communicate predictive values/outcomes as understood by Levinson's 167 system (See See Page 1 Section 0004, Page 3 Sections 0019-0025, and Page 4 Section 0039). Levinson 167 teaches a system not just a process, but a system that is more than capable of handling the process put forth by applicants, particularly the fact that the process put forth is programmed into a neural network as claimed by applicant, the same neural network that Levinson 167 teaches and is more than capable of automating and handling.

2) Claims 33-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Levinson (US PG Pub 2002/0177167).

Levinson 167 teaches a neural network (See Figure 6) that is capable of being trained through analysis of a plurality of crystallization experimental samples to predict optimal crystallization conditions for a protein. Furthermore the neural network could be programmed to be derive from the system a plurality of samples comprised of samples failing to yield crystals, depends on the operator's desired output.

3) Claims 35-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Levinson (US PG Pub 2002/0177167).

As previously stated Levinson 167 teaches a system that can be programmed and utilized for crystallization parameter optimization. The system may be comprised of a database and an incomplete factorial screen program i.e. programmed to handle such capabilities. However that is a recitation of intended use with respect to the physical components and structure of the system such as the computer (i.e. neural network), and manufacturing execution system that would be comprised of a robotic handler, imaging system, dispenser, sample centering, optical technology (See Page 9 Section 0066, 0076-0080). As argued before with respect to claims 1-16, 18-19, 21-29 and 31, Levinson 167's system is capable of doing so as claimed in claims 35-50, however this is a set of claims referring to the system and not the process, a system that is capable and these further parameters are recitation of intended use and bear no weight to the structural components of the system itself.

The amended changes to claim 35 incorporating the step process of variables being independent training variables thereafter having dependent variables which are the product of the independent training variables in the form of a plurality of crystallization experimental samples is taught by Levinson 167 (See Sections

0023-0024 and Abstract). Levinson 167 teaches an independent set of parameters which thereafter produce a series of results collected and pooled for a second set of parameters to depend from.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4) Claims 33-50 and 52 rejected under 35 U.S.C. 102(b) as being anticipated by Gester PCT Pub WO99/04361.

Examiner would like to note that he is using Gester (US 6,529,612) as an English equivalence to Gester PCT Pub WO99/04361.

Gester 612 pertains to a method and system for acquiring, storing, and analyzing crystal images. Wherein the reference teaches among many other things the following a data storage that reads on database and an incomplete factorial screen program i.e. programmed to handle such capabilities. However that is a recitation of intended use with respect to the physical components and structure of the system such as the computer (i.e. neural network), and manufacturing

execution system that would be comprised of an automated mechanism system, imaging system, dispenser, sample centering, optical technology (See Abstract, Figures 1-6, Cols 3-5 Lines 1-68 and Col 6 Lines 1-39). Gester 612's system is capable of doing as claimed in claims 35-50, however this is a set of claims referring to the system and not the process, a system that is capable and these further parameters are recitation of intended use and bear no weight to the structural components of the system itself.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 5) Claims 17, 20, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levinson (US PG Pub 2002/0177167) in view of applicant's admitted prior art on Pages 15 and 24 (Moloshok et. al. Application of Bayesian

Decomposition for analyzing microarray data and Carter Jr. et. al. Protein crystallization using incomplete factorial experiments).

Levinson 167 teaches a neural network and a system that is more than capable along with a process for optimal crystallization parameter determination. It may explicitly fail to teach the use or implementation of a Chernov algorithm/analysis or a Bayesian net/classification schema. But it is more than capable of being programmed and operating such parameters as can be further reinforced by applicant's admittance of prior publications and art related to that field.

Therefore at the time of the invention it would be obvious to one with ordinary skill in the art to implement such an algorithmic and analysis operation system on the neural network devised along with the system for optimal crystallization parameter determination as taught by Levinson 167 to further optimize the processing conditions.

Response to Arguments

6) Applicant's arguments filed 9/5/06 have been fully considered but they are not persuasive. Examiner respectfully submits that applicant's proposed amended changes to claims 1 and 35 do not overcome the teachings of the prior art put forth.

Examiner also respectfully submits that although the amended changes to claim 35 are similar to that of claim 1, the language does not delineate the fact that claim 35 references a system and not a method claim. Claims 35-50 pertain primarily to a system that needs to be capable of operating said parameters for which the method is viewed an intent of use, i.e. recitation of intended use.

Applicant's amended changes to differentiate currently what was claimed in claims 1 and 35 do not overcome the prior art since Levinson 167 teaches said limitation which can be understood from the abstract and Sections 0023-0024 of the specification.

Conclusion

7) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

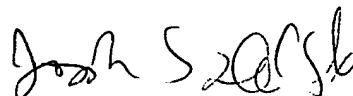
will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to G. Nagesh Rao whose telephone number is (571) 272-2946. The examiner can normally be reached on 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on (571)272-1316. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GNR


JOSEPH S. DEL SOLE
PRIMARY EXAMINER
9/15/06